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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/406,269    09/24/99    JIAO    J    48551

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HM12/0808

EXAMINER

VOLLAND, J

ART UNIT

PAPER NUMBER

1621

7

DATE MAILED:

08/08/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trad marks**

# Office Action Summary

Application No.  
09/406,269

Applicant(s)

Jiao et al

Examiner

Jean F Vollano

Group Art Unit  
1621



☐ Responsive to communication(s) filed on \_\_\_\_\_

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-63 is/are pending in the application.

Of the above, claim(s) 13-63 is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-12 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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### DETAILED ACTION

1. The election filed 6/28/00, paper no 6 has been entered. Applicant has elected Group II, claims 1 (in part), 2, and claims 5-12( in part), with traverse. Claims 3-4 and 13-63 are withdrawn from consideration as being drawn to non elected subject matter.

2. In reference to the traversal, Applicant requests that Group I and Group II and second Group II be rejoined. The examiner will rejoin the second Group II to the extent that it reads on the treatment of the diseases found in claim 2. The examiner will not rejoin Group I since it reads on any disease that is impacted by tissue factor. These are patentably distinct treatments from the treatments in the first Group II. It is also noted that since Group I reads on any disease that impacts TF and as such the claim reads on many diseases that are not enabled in the specification and therefore the inclusion of Group I would also introduce an enablement problem to the examination. However the enablement problem is not the reason for not rejoining the groups.

Groups I and II are patentably distinct and there is a burdensome search since Group I would entail a search of diseases (especially on line ) that are outside the search necessary for methods of treating the diseases listed in instant claim 2. The examiner will rejoin portions of the second Group II and as such examine claims 1(in part), 2 and 3-12( in part). Claims 3-4 will be examined to the extent that they read on the diseases given in instant claim 2. Claims 13-63 are withdrawn from consideration as being drawn to non elected subject matter.

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Applicant argues that the restriction includes 13 groups and this would be expensive and time consuming to pursue.

The examiner has given reasons on pages 5-7 of the office action filed 5/25/2000 why the restriction is proper. The only criteria for restriction is burdensome search and patentable distinction. The examiner has presented a case for patentable distinction and burdensome search in the written restriction and there has been no comment, by Applicant, on the reasons cited by the examiner. The restriction is proper for reasons cited in the office action of 5/25/2000 and MADE FINAL.

### *Claim Objections*

3. Claims 6-12 are objected to under 37 CFR 1.75© as being in improper form because they are multiply dependent and dependent on other multiple dependent claims . See MPEP § 608.01(n).

### *Claim Rejections - 35 U.S.C. § 112*

4. Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating a mammal for the diseases listed using compounds that are given in the specification as  $\text{Ar}-(\text{CXY})_m-(\text{Het})_{o \text{ or } 1}(\text{CX}^1\text{Y}^1)_n-\text{C}(\text{Z})_p-(\text{PO}_3)_{3-p}$  as TF blocking compounds , does not reasonably provide enablement for the method of treating a mammal using every compound regardless of structure that is or may be a TF blocking compound . The

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specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Finding all the compounds that can be used in the method of treating a mammal in need thereof would necessitate undue experimentation to 1) find out which compounds would be TF inhibitors, 2) how to make these compounds, and 3) how to effectively set up a regimen to use these compounds in the method being claimed. There are various methods of inhibiting and expressing tissue factor, such as complex binding formation or non binding inhibition. The various methods, known in the art, are far from being predictive of what compounds will and will not perform these functions by structural characteristics alone. There is no structural guidance given as to which compounds, outside those given above, would or would not be useful in the method of treatment being claimed.

It would take undue experimentation to use the invention as it is being claimed. The scope of the claims are broader than the scope of the enablement.

5. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation of "a disease impacted by tissue factor". It is unclear to what the "impacted" refers. Does "impacted" mean that the disease has a direct relationship with tissue factor? Does the term mean that disease is somehow vaguely associated with a response that

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would then show some relationship in a cascade which involves tissue factor? Does the term mean a disease which activates tissue factor or is in need of activating tissue factor? Does the term mean a disease which deactivates tissue factor ? Does the term mean that there is no direct relationship between the disease and that the method includes a secondary interaction ? The term is vague and indefinite as to the metes and bounds of what is being claimed in the instant invention.

Claim 7 recites the limitation of " compound comprises at least one phosphate group". It is unclear how a compound can comprise a group. A composition can comprise a group. If Applicant is trying to state that the compound has at least one phosphate as part of the structure it should be clearly and concisely stated. The claim is vague and indefinite as to the metes and bounds of what is being claimed. Claims 8-10 also have the same problem.

Regarding claims 11 and 12 , the phrase "preferably " renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

### ***Claim Rejections - 35 U.S.C. § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

7. Claims 1-9 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Chem abs 633 ( CA:126:324966).

Chem abs 966 teaches a compound of formula I wherein Ar is a optionally substituted heterocyclic compound, (CXY)<sub>m</sub> is ethylene , X is O, CZ<sub>p</sub> is ethylene and there is one phosphate group attached.

Chem abs 966 teaches the method of using the compounds in the treatment of cancer .

Chem abs 966 is silent as to the inhibition of tissue factor. However the compound meets the criteria for one that would inhibit tissue factor and as such the compound would inherently meet the limitations of the instant claims when used in the method for treatment of cancer as taught by Chem abs 966.

8. Claims 1-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Hartmann et al (US5854227).

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Hartmann et al teaches compounds which are useful in the treatment of cancer that contains a diphosphinate moiety (that is known a chelating agent in the art) (see abstract).

Hartmann et al teaches that the compounds can be used in the treatment of cancer (see abstract) .

Hartmann is silent as to the inhibition of tissue factor. However the compound being used in the treatment is a diphosphate moiety which would act similarly ( i.e. chelator etc) to the disclosed compounds and would inherently meet the limitations of the instant claims.

9. Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Lehtinen et al (US5403829).

Lehtinen et al teaches compounds which are useful in the treatment of cancer that contains a diphosphinate moiety (that is known a chelating agent in the art) (see abstract).

Lehtinen et al teaches that the compounds can be used in the treatment of eliminating complications from bone surgery (see abstract) .

Lehtinen et al is silent as to the inhibition of tissue factor. However the compound being used in the treatment is a diphosphate moiety which would act similarly ( i.e. chelator etc) to the disclosed compounds and would inherently meet the limitations of the instant claims.

10. Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Chem abs 356 (CA:127:5356).



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Chem abs 356 teaches a peptide containing a peptide which are useful in the treatment of arteriosclerosis .

When Chem abs 356 teaches that the peptides are inhibitors of the tissue factor pathway and the method of using the compounds then the claims are fully anticipated.

11. Claims 1-12 are rejected under 35 U.S.C. 102(a) as being anticipated by Chem abs 820 (CA:130:209820).

Chem abs 820 teaches a compound of formula I wherein Ar is a phenyl group or an heteroaryl group ,  $(CXY)_m$  is 0-3 , X is S, NH or doesn't exist ,  $CZ_p$  is 1-3 and there two phosphate groups attached.

Chem abs 820 teaches that the a method of using the compounds in the treatment of cardiovascular disorders .

Chem abs 820 is silent as to the inhibition of tissue factor. However the compound meets the criteria for one that would inhibit tissue factor and as such the compound would inherently meet the limitations of the instant claims in that it would be usable in a method of treatment described and would inherently be a tissue factor blocking agent.

12. Claims 1-6 are rejected under 35 U.S.C. 102(a) as being anticipated by Chem abs 249 (CA:125:212249).

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When Chem abs 249 teaches the method of using heparin as an anticoagulant which is related to release of tissue factor pathway inhibitors the claims are fully anticipated.

13. Claims 1-6 are rejected under 35 U.S.C. 102(a) as being anticipated by Chem abs 717 (CA:124:45717).

When Chem abs 717 teaches the method of using the compounds disclosed as an therapeutic agent which inhibits tissue factor and the method of using the compounds then the claims are fully anticipated.


14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr J F Vollano whose telephone number is (703) 305-4483. The examiner can normally be reached on Monday to Thursday from 6:30 to 5:00 .

15. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter , can be reached on (703)308-4532 . The official fax phone number for the organization where this application or proceeding is assigned is (703)308-4556. It should be noted that the examiner cannot immediately work on a fax sent to this number.

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16. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-1235.

Jean F. Vollano

A handwritten signature in black ink, appearing to read "Jean F. Vollano", written in a cursive style.

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August 3, 2000